

Mitchell E. Daniels, Jr. Governor

Gregory N. Larkin, M.D., F.A.A.F.P. State Health Commissioner

DATE:

September 20, 2010

TO:

All Local Health Departments

Attn: Chief Food Inspection Officer

FROM:

A. Scott Gilliam, MBA, CP-FS

Director, Food Protection Program

**SUBJECT:** 

Genetic Edge Technologies Recall

## SUGGESTED

**ACTION:** 

Unclassified Recall; 60 count bottles of ArimaDex, because it may contain an

Aromatase Inhibitor; Recommend notification of affected stores via phone, fax or e-

mail.

From the information provided by FDA, the product being recalled may be distributed in the State of Indiana. ArimaDex was distributed throughout the United States to national sports supplements distributors and could be purchased by consumers via retail stores, mail order and internet sales. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-

7360.

\*

## **Recall -- Firm Press Release**

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

## G.E.T. Issues Vouluntary Recall of ArimaDex

## Contact:

Genetic Edge Technologies, Inc 1-480-248-7957 FOR IMMEDIATE RELEASE -- September 13, 2010 - Genetic Edge Technologies of Phoenix, Arizona is voluntarily recalling 60 count bottles of ArimaDex, because it may contain an Aromatase Inhibitor. Genetic Edge Technologies has been informed by the US Food and Drug Administration (FDA) that potential adverse events associated with the use of Aromatase Inhibitors could include the following: decreased rate of bone maturation and growth, decreased sperm production, infertility, aggressive behavior, adrenal insufficiency, kidney failure, and liver dysfunction. Consumers with liver, kidney, adrenal, or prostate abnormalities are at a potentially higher risk for developing adverse events. The FDA concludes that products containing aromatase inhibitors have an increased probability of developing adverse reactions in at risk consumers.

ArimaDex was distributed throughout the United States to national sports supplements distributors and could be purchased by consumers via retail stores, mail order and internet sales.

Arimadex comes in white bottles with orange labels containing 60 orange soft gels. Arimadex is sold with UPC Code 718122466511 appearing on the label. All lot numbers of ArimaDex are being affected by this voluntary recalled.

Genetic Edge technologies has received no reports of any types of any adverse event or illnesses since first marketing ArimaDex in Feb 2009.

Consumers who have purchased ArimaDex are urged to return it to the place of purchase for a full refund. Consumers with questions may contact the company at 1-480-248-7957 during the hours of 9AM – 2PM M-F.

Adverse reaction or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, or by fax. Online: www.fda.gov/MedWatch/report.htm. Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form. Fax: 1-800-FDA-0178.

#

Photo: Product Label<sup>9</sup>